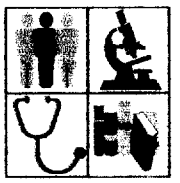

Infectious Diseases Society of America

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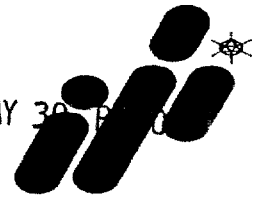

Pediatric Infectious
Diseases Society

May 30, 2000

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: [Docket No. 00D-1223] International Conference on Harmonization; E11: Clinical Investigation of Medicinal Products in the Pediatric Population

To whom it may concern:

The Infectious Diseases Society of America (IDSA) and Pediatric Infectious Diseases Society (PIDS) welcome the opportunity to comment on the Food and Drug Administration's (FDA) draft guidance entitled "E11: Clinical Investigation of Medicinal Products in the Pediatric Population." IDSA is a medical society representing over 5000 physicians and scientists devoted to patient care, education, research, and community health planning in infectious diseases. PIDS is an organization of over 900 physicians, doctoral-level scientists, and other persons who have training or are in the course of training, in infectious diseases or its related disciplines and who are identified with the discipline of pediatric infectious diseases or its related activities. PIDS works to enhance the health of infants, children and adolescents by promoting excellence in diagnosis, management and prevention of infectious diseases through clinical care, education, research and advocacy.

Both IDSA and PIDS are very interested in the timely development of pediatric medicinal products. We support the work undertaken by the International Conference on Harmonization's Expert Working Group on Efficacy in preparing this draft guidance and look forward to final FDA guidance that encourages pediatric drug development and approaches to the safe, efficient, and ethical study of medicinal products in the pediatric population. IDSA and PIDS offer the following few comments on the document that we believe will help to better achieve these outcomes:

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1) Section 2.2 Pediatric Formulations. The following should be added: "thimerosal-free, preservative-free medicinals are optimal for use in pre-term and term neonates and infants."

2) Section 2.4 Types of Studies, (Para 2, sentence one). The following new second sentence should be added: "This should be decided on a disease-by-disease basis."

3) Section 2.6.5 Minimizing Distress. "-- Indwelling catheters rather than repeated venipunctures for blood sampling" is fine for short term (e.g. hours) and while the patient is observed. We suggest adding: "Duration of catheterization must be limited to minimize risks of infection, thrombosis and inadvertent **discon**nection leading to unobserved hemorrhage. Additionally, withdraw**al of larg**er volumes of blood, which is necessary to avoid dilutional artifacts, must still fall into acceptable limits."

Thank you for the opportunity to comment on this very important document.

Sincerely,

Catherine M. Wilfert, M.D.
President, IDSA

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VIA COURIER SERVICE